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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,657	07/31/2001	Michael S. Freund	06618-675001	4654

7590 11/10/2003

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,657	FREUND ET AL.	
	Examiner	Art Unit	
	Kaj Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,5-10,17,20,23-25,28,29,31,35-40,45,46,48,51,54-56,59,61 and 62 is/are rejected.
- 7) ☒ Claim(s) 2-4,11-16,18,19,21,22,26,27,30,32-34,41-44,47,49,50,52,53,57,58 and 60 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2/25</u> . | 6) <input type="checkbox"/> Other: _____ |

ETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On pages 1 and 6 of the disclosure, there are blank spaces where application numbers should be entered. Applicant should amend the specification to include those application numbers, or where possible the patent numbers associated with the application numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 24 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 31 set forth either the step of detecting a response of a sensor based on a change in the pKa of the polymer, or a detector configured for detecting a response based on a change in the pKa of the polymer. Claims 24 and 55 (which depend from claims 1 and 31 respectively) set forth that the detected response to be a change in mass. It is unclear to one possessing ordinary skill in the art how one could determine whether a change in pKa has occurred based on a change in mass of the sensor. It would seem that mass would be unrelated to the pKa of the polymer (unlike impedance, color,

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pH, potential, and conductivity, which the examiner concurs would be related to the pKa of the polymer). How would mass be an indicator of whether or not the pKa of the polymer had changed?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-10, 17, 20, 23, 25, 28, 29, 31, 35-40, 45, 46, 48, 51, 54, 61, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Pringsheim et al (Analytica Chimica Acta 357 (1997) pp. 247-252).

6. Pringsheim discloses a method of detecting an analyte in a fluid where a sensor having a polymer (polyaniline), which the instant invention evidences is capable of undergoing a proton-coupled redox reaction (see abstract). Pringsheim further discloses the use of substituents (e.g. immobilized urease) capable of undergoing a reaction with an analyte (urea) (section 2.3 on pp. 248 and 249). Pringsheim further discloses exposing the sensor a fluid containing the analyte and detecting the response to the exposure of the sensor to the analyte based on a change in the pKa of the polymer (abstract, and sections 3.3, 3.4, and 3.7 on pp. 250-252).

7. With respect to whether the reactive substituent has an inductive or resonance effect on the pKa, it would appear that these are inherent properties of the choice of polymer set forth by Pringsheim.

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8. With respect to the choice of polymers, see tables 1 and 3.
9. With respect to the sensor system (those limitations not covered above), Pringsheim teaches the use of fluid volume (i.e. a cuvette) (section 3.2).
10. With respect to the system claims and the choice of analyte, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
13. Claims 56 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pringsheim in view of Kikuchi et al (Analytical Chemistry, 1996, 68, pp. 823-828).

14. Pringsheim discloses all the limitations of the claim, but does not explicitly recite the presence of a programmable processor coupled to the detector. Kikuchi discloses in an alternate sensor the use of a programmable processor for coupling to the detector device (fig. 2), which would allow for automation of the sensing operation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kikuchi for the system of Pringsheim in order to automate the analysis process.

Allowable Subject Matter

15. Claims 2-4, 11-16, 18, 19, 21, 22, 26, 27, 30, 32-34, 41-44, 47, 49, 50, 52, 53, 57, 58 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not disclose nor render obvious all the limitations of claims 1 or 31 with said method or system further comprising any one of (a) a plurality of reactive substituents including two or more chemically different reactive substituents, (b) a poly (aniline boronic acid) polymer, (c) the reactive substituents of claims 13 or 44, (d) one or more reversible substituents, (e) a response based on change in electrochemical potential, conductivity, or impedance, or (f) the set forth distinguishing step (or processor operable for) of claims 26, 27, 57, 58, or 60. The prior art further does not disclose nor render obvious the method of claim 1 and further comprising the set forth analytes of claims 14 and 15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
November 6, 2003